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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
NGUYEN, QUANG

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,293	FREYMAN ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-41 are pending in the present application.

Upon further consideration, the species restriction requirement mailed on 12/16/2004 is vacated. The pending claims are subjected to the following new election/restriction requirement.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction:

I. Claims 1-2, 5-15, 27-28, 30 and 35, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted before the harvesting step (c) ***(in vivo or in situ conditioning)*** and wherein the body tissue is conditioned by **genetic engineering or a biological conditioning process**, classified in class 514, subclass 44.

II. Claims 1-2, 5-14, 16 and 35, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted before the harvesting step (c) ***(in vivo or in situ conditioning)*** and wherein the body tissue is conditioned by **a chemical conditioning process**, classified in class 435, subclass 375.

III. Claims 1-2, 5-14, 17 and 35, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted before the harvesting step (c) **(*in vivo or in situ* conditioning)** and wherein the body tissue is conditioned by **a pharmaceutical conditioning process**, classified in class 424, subclass 198.1, 85.1; class 514, subclass 2, for examples.

IV. Claims 1-2, 5-14, 18 and 35, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted before the harvesting step (c) **(*in vivo or in situ* conditioning)** and wherein the body tissue is conditioned by **a physiological conditioning process**, classified in class 435, subclass 1.3, for example.

V. Claims 1-2, 5-14, 19-20, 31-32 and 34-35, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted before the harvesting step (c) **(*in vivo or in situ* conditioning)** and wherein the body tissue is conditioned by **a mechanical conditioning process**, classified in class 600, subclass 9, for example depending on the type of mechanical force applied *in vivo*.

VI. Claims 1, 3-15, 27, 29-30 and 35-36, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted after the harvesting step (c) **(*in vitro* conditioning)** and wherein the body tissue is conditioned by **genetic engineering or a biological conditioning process**, classified in class 435, subclass 455, for example.

VII. Claims 1, 3-14, 16 and 35-36, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted after the harvesting step (c) **(*in vitro* conditioning)** and wherein the body tissue is conditioned by **a chemical conditioning process**, classified in class 435,subclass 375.

VIII. Claims 1, 3-14, 17 and 35-36, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted after the harvesting step (c) **(*in vitro* conditioning)** and wherein the body tissue is conditioned by **a pharmaceutical conditioning process**, classified in class 435, subclass 325.

IX. Claims 1, 3-14, 18 and 35-36, drawn to a method for producing a decellularized extracellular matrix material containing a biological material,

wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted after the harvesting step (c) **(*in vitro* conditioning)** and wherein the body tissue is conditioned by **a physiological conditioning process**, classified in class 435, subclass 375, for example.

X. Claims 1, 3-14, 19-20, 31 and 33-36, drawn to a method for producing a decellularized extracellular matrix material containing a biological material, wherein the method comprises steps (a)-(d) of claim 1, and wherein steps (a) and (b) are conducted after the harvesting step (c) **(*in vitro* conditioning)** and wherein the body tissue is conditioned by **a mechanical conditioning process**, classified in class 435, subclass 375.

XI. Claims 21-22 and 37-41, drawn to a decellularized extracellular matrix material or a tissue regeneration scaffold for implantation into a patient comprising the decellularized extracellular matrix material produced by the method of claim 1, and an implantable medical device comprising a surface and a decellularized extracellular matrix material comprising a biological material, classified in class 424, subclasses 520, 422, for examples.

XII. Claims 24-26, drawn to a method of using the decellularized extracelluar matrix material produced by the method of claim 1 to repair, to regenerate or to strengthen injured body tissue of a patient, classified in class 424, subclasses 422, 484, for examples.

Claims 1-20 and 27-36 link a plurality of distinct inventions of Groups I to X. This is because a method for producing a decellularized extracellular matrix material containing a biological material encompasses distinct methods that have distinct method steps that require different starting materials and different technical considerations for achieving the same desired result. For example, the methods of Groups I-V require *in vivo* or *in situ* conditioning body tissue of a donor animal, whereas the methods of Groups VI-X require *in vitro* conditioning body tissue of a donor animal. Furthermore, the body tissue is conditioned by distinct processes that include a genetically engineering or a biological conditioning process (Groups I and VI), a chemical conditioning process (Groups II and VII), a pharmaceutical conditioning (Groups III and VIII), a physiological conditioning process (Groups IV and IX), and a mechanical conditioning process (Groups V and X) that are distinct one from the others.

Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

See In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132(CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I to X are drawn to distinct methods that have distinct method steps that require different starting materials and different technical considerations for achieving the same desired result as already discussed above.

Inventions I-X and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, a decellularized extracellular matrix material of Group XI can be produced by any one of a plurality of distinct methods in Groups I-X, or by a different process involving culturing cell lines, followed by a decellularizing process to yield a decellularized extracellular matrix material containing a biological material.

Inventions XI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a decellularized extracellular matrix material of Group XI can be used to produce an implantable medical device or as a substrate for cell cultures.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements due to the distinct method steps as well as the distinct conditioning processes of Groups I-X, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction:

A. Should Applicants elect any one of Groups I-X, this application contains claims directed to the following patentably distinct species of a body tissue of the claimed invention:

A specifically named body tissue as recited in the Markush group of claim 12.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 12 are generic.

B. Should Applicants elect any one of Groups I-X, this application contains claims directed to the following patentably distinct species of a biological material of the claimed invention:

A specifically named biological material as recited in the Markush group of claim 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 13 are generic.

C. Should Applicants elect any one of Groups I-X, this application contains claims directed to the following patentably distinct species of a donor animal of the claimed invention:

A specifically named mammal as recited in the Markush group of claim 10.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 10 are generic.

D. Should Applicants elect either Group V or Group X, this application contains claims directed to the following patentably distinct species of mechanical conditioning of the claimed invention:

A specifically named applied force as recited in the Markush group of claim 20.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 14 and 19-20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

QUANG NGUYEN, PH.D
PATENT EXAMINER